

Texas Natural Resource Conservation Commission

INTEROFFICE MEMORANDUM

To:	Distribution	Date:	December 11, 2001
Thru:	JoAnn Wiersema, Manager Toxicology & Risk Assessment Section Office of Permitting, Remediation & Registration		
From:	Michael Honeycutt, Ph.D. Toxicology & Risk Assessment Section Office of Permitting, Remediation & Registration		
Subject:	Technical Justification for a Revised Interim Action Level for Perchlorate		

On October 5, 2001, the Toxicology & Risk Assessment Section (TARA) revised its recommended interim drinking water action level for perchlorate from 22 $\mu\text{g/L}$ (ppb) to 4 ppb. This memorandum provides the technical justification for this change. Perchlorate presents the TNRCC with some unique challenges in that the Agency is trying to make important regulatory decisions in the midst of rapidly developing science. Further compounding the importance of the decisions and the need for the data is that, based on perchlorate's mechanism of action, short-term exposures to perchlorate can lead to permanent adverse health effects.

Background

Perchlorate gained widespread attention in 1997 when the California Department of Health Services developed an analytical method for perchlorate which lowered the quantitation limit for perchlorate from 400 ppb to 4 ppb. Regulatory agencies and potentially responsible parties then began to detect perchlorate in areas where it had previously either not been detected or not been a concern. The United States Environmental Protection Agency (USEPA) and the United States Department of Defense (DoD) began to conduct toxicological research on perchlorate to generate data to develop toxicity factors, specifically a reference dose (RfD), for perchlorate.

While the toxicity studies were ongoing, USEPA recommended that states and USEPA regions use the provisional reference dose range (0.0001 mg/kg-day to 0.0005 mg/kg-day) developed by USEPA's National Center for Environmental Assessment (NCEA) in 1995. However, in December of 1998, USEPA published an external review draft document containing a new provisional RfD of 0.0009 mg/kg-day for perchlorate using the new toxicological data generated by USEPA and DoD. TARA reviewed this new RfD and considered it appropriate to use as the basis for a drinking water interim action level. Using the child exposure factors prescribed in the Texas Risk Reduction Program (TRRP) rule (0.64 L/day drinking water ingestion rate and 15 kg bodyweight), the acceptable drinking water value derived using the newer provisional RfD was determined to be 22 ppb. This 22 ppb value was selected as the TNRCC interim action level for drinking water as described in the TARA June 28, 1999 memorandum (see attachment 1) and also as a TRRP groundwater ingestion Protective Concentration Level (PCL) and as a Risk Reduction Rule (RRR) Standard 2 residential groundwater Medium Specific Concentration (MSC).

In June of 1999, USEPA released a memorandum (see attachment 2) indicating that an external scientific peer review panel recommended that the perchlorate toxicity data be re-reviewed using thyroid hyperplasia for the determination of the reference dose rather than thyroid hypertrophy. Additionally, they recommended that more toxicity tests (i.e. immunotoxicity tests) be conducted to reduce some of the uncertainty of the new RfD. In the 1999 memorandum, USEPA also recommended that the 1995 reference dose range of 0.0001 mg/kg-day to 0.0005 mg/kg-day be used until USEPA released a new RfD incorporating the new toxicity test data and the re-evaluation of the thyroid pathology data. TARA decided to continue to use the 22 ppb interim action level since the new provisional RfD was based on the best available toxicity data.

This 22 ppb value was also used as a human health surface water quality criterion. Human health surface water quality criteria generally consider two pathways: 1) ingestion of drinking water and 2) consumption of fish that have bioaccumulated the chemical of concern. The 22 ppb human health surface water quality criterion considered only ingestion of drinking water. Since perchlorate is an anion, bioaccumulation in fish was not considered an issue at the time. The TNRCC considered promulgating the 22 ppb human health surface water quality criterion as a Texas surface water quality standard in the last triennial review of the water quality standards which were adopted July 26, 2000. However, the agency decided to not promulgate a water quality standard, but to address perchlorate issues in surface water on a site-specific basis via a site-specific water quality standard.

It is important to note that surface water quality criteria and standards are generally in-stream values and are not typically applied as discharge criteria. Rather, they are typically used to derive a water-quality based discharge criterion which incorporates a mixing zone. Also, if treatment technology is available which can treat effluent to a level lower than the water-quality based criterion, then the treatment-technology based criterion would apply.

Development of the 4 ppb Interim Action Level

Subsequent to the development of the 1998 provisional RfD and the 1999 USEPA memorandum recommending the use of the 1995 NCEA range of RfD values, newer toxicity and tissue residue data have been developed. This new information, along with several additional considerations, led the TNRCC to develop a new interim action level for perchlorate. The development of the 4 ppb interim action level was based on a weight-of-the-evidence approach (i.e. a number of factors were considered in making the decision). These factors are outlined below:

(1) USEPA is currently recommending use of NCEA's 1995 provisional reference dose range of 0.0001 mg/kg-day to 0.0005 mg/kg-day. Current toxicological studies (subsequent to the 1998 provisional RfD) indicate the potential for developmental and neonatal impacts from perchlorate which could result in an acceptable drinking water value *at the lower end* of the 1995 provisional RfD range (USEPA, 2001). USEPA toxicologists are developing a new RfD for perchlorate incorporating the new toxicology studies and the re-evaluated thyroid pathology data. The new RfD should be available for public review early next year.

(2) USEPA Region 9 in July of 2001 issued a Superfund Record of Decision for the Aerojet Sacramento Site in Rancho Cordova, California in which they established a groundwater cleanup value and a surface water discharge criterion of 4 ppb for perchlorate. The groundwater cleanup value was derived using a RfD of 0.0001 mg/kg-day and adult exposure factors. The toxicology

studies mentioned in point 1 above are part of the rationale behind USEPA Region 9's selection of the 4 ppb cleanup value. The 4 ppb discharge criterion is a treatment-technology based discharge criterion.

(3) USEPA Region 1 in July of 2001 established a perchlorate groundwater cleanup level of 1.5 ppb for Camp Edwards in Massachusetts. This cleanup level was derived using a RfD of 0.0001 mg/kg-day and child exposure factors (1 L/day drinking water ingestion rate and 15 kg body weight). USEPA Region 1's justification for the cleanup level also references the new toxicology data: "...because EPA believes important new studies that were not available in 1999 are either underway or planned and are anticipated to have in [sic] impact on the proposed human health risk benchmark..." (see attachment 3). However, it is unclear how perchlorate's analytical detection limit will affect this cleanup level as current detection limits are higher than this cleanup level.

(4) Texas Tech University, in cooperation with the Brazos River Authority and the US Army Corps of Engineers, has collected fish samples from waterbodies adjacent to the NWIRP McGregor facility for perchlorate analysis. Perchlorate levels in fillets from bass, sunfish, and catfish ranged from 260 to 690 ppb, which could pose a potential health concern if ingested. Using a RfD of 0.0001 mg/kg-day, a body weight of 70 kg, and a fish ingestion rate of 30 g/d, an acceptable fish tissue concentration that would be protective of human health would be about 200 ppb. In addition, perchlorate levels in the heads of suckers and sunfish were in the 1000 ppb range. The possibility of ecological effects are also a concern. However, the data are variable and are not adequate to derive a bioaccumulation factor (a factor used to predict uptake of a chemical into fish from water). While these data would not necessarily directly impact a drinking water value, they would impact surface water criteria for perchlorate.

(5) Another consideration in setting the interim action level for perchlorate is the current state of analytical capabilities. The only USEPA method currently approved for perchlorate analysis in water is Method 314, which has a reporting limit of 4 ppb. Various research groups have developed new analytical techniques for perchlorate, including an ion chromatographic method which employs a prefilter to remove interfering ions and an ion chromatographic/mass spectrometric method, which will lower the reporting limit even further.

Taking all of the above information into consideration, TARA selected the 1995 NCEA RfD range (0.0001 mg/kg-day to 0.0005 mg/kg-day) as the basis for the TNRCC drinking water interim action level, groundwater cleanup values, and human health surface water quality criterion. Using child exposure factors (0.64 L/day drinking water ingestion rate and 15 kg bodyweight) from the TRRP rule in conjunction with the 1995 NCEA RfD range, a range of acceptable drinking water values of 2.4 to 12 ppb is calculated. Given the weight of the evidence described above and that the analytical method currently approved by USEPA has a reporting limit of 4 ppb, the perchlorate interim action level was set at 4 ppb which is at the lower end of this range. We have consulted with USEPA toxicologists on an ongoing basis regarding perchlorate toxicology issues for several years and they concur with our recommendation of using the lower, more conservative end of the RfD range.

In summary, TARA is now recommending that the TNRCC use 4 ppb as an interim action level for perchlorate in drinking water, as well as a human health surface water quality criterion. This value is at the lower end of the range of values currently recommended by USEPA and is similar

to cleanup values established by USEPA Regional offices. The value is scientifically defensible; it is health protective; and it is consistently and accurately detectable using current analytical techniques.

If you have any questions, please call me at 512-239-1793.

Reference:

USEPA. 2001. Record of Decision for the Western Groundwater Operable Unit OU-3. Aerojet Sacramento Site, Rancho Cordova, California. USEPA Region 9. San Francisco, California.

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Attachment 1